

technical files of the various subcomponents used to assemble this PAEG. This may help shorten the regulatory path by minimizing the amount of testing required.

Limitations of this study include its retrospective nature and lack of a control group. Because of the small number of patients, we were not able to perform statistical analysis.

## CONCLUSIONS

There are few medical maladies that have challenged our specialty like the management of TAAAs. The layers of complexity of this problem continue to grow as our treatment options expand. Historically, only a small number of patients with this problem were deemed fit enough to undergo open repair. Only a handful of centers could generate sufficiently reasonable and predictable outcomes to justify considering such an extensive repair. With the introduction of endovascular repair, we have opened the door to treating more patients but have not necessarily expanded the number of centers.

There is a need for a technique that empowers physicians with a safe and simple way to treat these patients closer to home while being able to maintain predictable outcomes. The ideal endovascular system needs to be modular so as to be an off-the-shelf system. Its configuration needs to be nonanatomically based to widen the range of anatomic configurations that can be treated. It must also have “surgical bailouts” that allow the surgeon to be able to stop the procedure at any point in the case while not leaving the patient with compromised perfusion to any organ system. We think that this approach, which makes use of delayed distal seal, does this. It simplifies case planning by requiring only one measurement to be made in the proximal seal zone; it can be used in an off-the-shelf way, and it can accommodate a large variety of anatomies.

## AUTHOR CONTRIBUTIONS

Conception and design: PK, TR  
Analysis and interpretation: PK, TR, MN, JA  
Data collection: TR, PK, MN, JA, LD  
Writing the article: TR, PK, MN, JA, LD  
Critical revision of the article: TR, PK  
Final approval of the article: PK  
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## INVITED COMMENTARY

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The authors present a unique endovascular solution for the treatment of thoracoabdominal aortic aneurysms (TAAA) involving alteration and assembly of commercial endografts by

the physician. The manuscript can be added to the growing body of literature describing “creative techniques” to provide endovascular treatment of TAAA, which include the use of

off-the-shelf components to construct chimneys, periscopes, and sandwiches as well as other direct physician modification of commercial grafts.<sup>1-3</sup> The evolution of these techniques is sparked by an apparent clinical need. Only one commercial fenestrated endograft is available, and its use is limited by the need for customization, a short infrarenal neck, and dissemination of physician training. Off-the-shelf devices have reached clinical trials, but none has yet obtained commercialization, and many have limited application to treat extensive TAAA. Currently, outside of the creative techniques, endovascular repair of TAAA requires the use of custom-made devices (and some off-the-shelf designs) that are available only at a few centers nationwide as part of physician-sponsored investigational device exemption trials. Treatment in these trials is frequently difficult for patients because of the time and expense of travel and the potential denial of insurance coverage.

Whereas creative techniques offer a potential alternative to custom devices, many questions remain unanswered with respect to this approach: Which patients are suitable candidates? Are the repairs durable? Can and should these techniques be readily adapted by everyone? Can health care systems support the costs associated with use of multiple devices? Despite their shortcomings, customized fenestrated/branched endografts have been closely evaluated during long periods and provide a durable repair in patients who are at high risk for surgery with outcomes that rival those of conventional operations.<sup>4-6</sup> Outcomes are reported from physician-sponsored investigational device exemption trials with well-defined patient and anatomic enrollment criteria with standard clinical and imaging follow-up protocols. This type of data is lacking for any of the creative techniques. They should, however, be held to the same standard. If creative techniques are to be accepted as durable options, we must evolve from reporting

techniques in a few patients with limited outcomes and instead direct efforts toward understanding patient selection, improving graft modification techniques, predicting those at risk for failure, and determining whether these techniques can be readily disseminated. The ramifications of failure with endovascular TAAA repair are great and need to be avoided. Only a well-planned assessment of robust data will allow us to answer these questions, to assess the modes of failure, and to determine whether these approaches are in our patients' best interests. Future endeavors, in an organized fashion, are necessary to achieve these goals.

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